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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,773	11/28/2001	Yoshinobu Hanyu	P21651	9572

7055 7590 05/24/2004

GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/994,773

Applicant(s)

HANYU ET AL.

Examiner

Joyce Tung

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The applicant's response filed 2/24/2004 to the Office Action has been entered. Claims 1-24 are pending. In addition, the case has been reassigned as the previous examiner has left the office.

1. The claims 1-24 remain rejected under 35 U.S.C. 112, second paragraph. Because based upon the amendment of claim 1, the phrase "binder" is still unclear what is the class of molecules consisting the binder. Clarification is required.
2. The rejection of claims 10 and 22 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment.
3. Claims 1, 3, 5-6, 8, 10-13, 15, 17, 20, 23 and 24 remain rejected under 35 U.S.C. 102(b) as being anticipated by Samaritani (WO 95/35116, issued December 28, 1995).

The response argues that Samaritani teaches using saccharose as a stabilizing agent and Saccharose is neither a nonionic surfactant, a nonionic, organic, water-soluble binder, hydrogenated lecithin or mannitol. However, the limitations of the claim do not require saccharose used as a stabilizing agent. Thus the teachings of Samaritani read on the limitations of the claims. Therefore, the rejection is maintained.

The response further argues that Samaritani does disclose the use of mannitol with a physiological active peptide; Samaritani does not discuss whether mannitol also stabilized the resultant powder. However, Samaritani indicates that human growth hormone formulations is stabilized with stabilizing excipients such as mannitol (See pg. 2, lines 1-6, 18-20 and 27-28).

Thus Applicant's arguments filed 2/24/2004 have been fully considered but they are not persuasive. The rejection is maintained.

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Claim 22 is also rejected under 35 U.S.C. 102(b) as being anticipated by Samaritan (WO 95/35116, issued December 28, 1995).

Since Samaritani teaches formulation with human growth hormone (See pg. 5, lines 7-14). Thus, the teachings of Samaritani anticipate the limitation of claim 22.

4. Claims 1, 7, 13 and 19 remain rejected under 35 U.S.C 102 (b) as being anticipated by Bjorn et al. (WO 97/39768, issued October 30, 1997).

The response argues that Bjorn et al. do not teach a method of using a non-ionic detergent polysorbate or poloxamer, instead teaches its use in combination with a certain amino acid sequence or peptide having specific features. However, since the instant invention is presented with open language “comprises”, the open language of the claims allows for other components.

The response further argues that Bjorn does not teach stabilizing a physiologically active peptide by using the surfactant and the specific amino acid sequence or peptide having specific features during the powder formation process. However, Bjorn does teach the physiologically active peptide is in the form of a lyophilized powder (See pg. 11, lines 1-3 and lines 9-10) Thus, Applicant's arguments filed 2/24/2004 have been fully considered but they are not persuasive as discussed above. The rejection is maintained.

5. The rejection of claims 9 and 21-22 under 35 U.S.C. 103(a) over Samaritani (WO 95/35116, issued December 28, 1995) in view of Shigehara et al. (5,763,439 issued June 9, 1998) is withdrawn.

6. Claim 18 remains rejected under 35 U.S.C. 103(a) over Samaritani (WO 95/35116, issued December 28, 1995) in view of Morita et al. (6,156,343, issued December 5, 2000).

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The response argues that Morita et al. disclose a method of making a tablet and teach covering the tablet with hydroxypropylmethylcellulose to protect the tablets from light. However, the claim language does not require any particular function of the hydroxypropylmethylcellulose that can be broadly interpreted as stabilizing the preparation. Nevertheless Morita et al. disclose that the use of hydroxypropylmethylcellulose is for stabilizing the drug. One of ordinary skill in the art would have been motivated to apply hydroxypropylmethylcellulose to the powder composition of Samaritani et al. because powder is another form of medicine. Thus, Applicant's arguments filed 2/24/2004 have been fully considered but they are not persuasive as discussed above. The rejection is maintained.

#### **NEW GROUNDS OF REJECTIONS**

##### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 9 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 9 and 21 are vague and indefinite because the phrase "particle" in claims 9 and 21 has no antecedent basis. Furthermore, it is unclear whether or not the "particles" are additionally added to the powder for preparing the powder. Clarification is required.

##### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2, 4, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samaritani (WO 95/35116, issued December 28, 1995) in view of Bjorn et al. (WO 97/39768, issued October 30, 1997).

Samaritani discloses a process for preparing the pharmaceutical composition containing hGH with mannitol (See pg. 3, lines 2-9). The powder is made up of particles comprising hGH and mannitol is at a weight proportion of 1:1 to 1:50 (See pg. 5, Table 1).

Samaritani also discloses that the particles further comprise a water-soluble, nonionic, organic binder in an amount of 6 parts (precisely 5.93 parts) by weight (See pg. 5, Table 1) and drying of the aqueous liquid was performed by lyophilization (See PG. 5, lines 1-2).

Samaritani does not disclose adding another compound selected from the group of a nonionic surfactant, a nonionic, organic, water-soluble binder and hydrogenated lecithin.

Bjorn discloses that the invention relates to pharmaceutical formulations comprising growth hormone and a non-ionic detergent, e.g. polysorbate or poloxamer (See the abstract).

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One of ordinary skill in the art would have been motivated to add a non-ionic detergent, e.g. polysorbate (See pg. 8, lines 11-14) to the method of the stabilization of a physiologically active peptide. As indicated by Bjorn, the non-ionic detergent is used for stabilization against deamination and aggregation of the peptide (See pg. 7, lines 1-9). It would have been prima facie obvious to add a non-ionic detergent in the method for the stabilization of a physiologically active peptide.

### **SUMMURY**

12. No claims are allowable.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

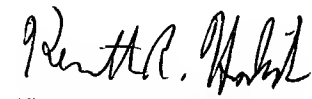
Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

May 6, 2004

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

5/17/04